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## Fight Colorectal Cancer Statement on the U.S. Drug Shortage

September 23, 2011

There are severe shortages of more than 100 life-saving drugs in the United States – several of which are key to treatments for colorectal cancer patients: leucovorin, fluorouracil (5-FU), and irinotecan. Over the past 10 years, rolling drug shortages are becoming more frequent and likely will worsen.

There *is* a substitute for leucovorin. A significantly more expensive new brand-name drug, *Fusilev*, has been added to national care guidelines, which should facilitate coverage, at least in part, by Medicare and private insurers. National guidelines also suggest use of lower doses of leucovorin, or, as a last resort, treatment without leucovorin can be considered when combined with a possible increase in 5-FU dosage. However, 5-FU is now also in short supply.

“For patients living with colon and rectal cancer, this is a crisis. We have spoken with a patient with late stage rectal cancer in California who was unable to be treated for his cancer because of the 5-FU shortage,” said Carlea Bauman, president of Fight Colorectal Cancer. “Another patient with curative disease was unable to get his recommended treatment because of the leucovorin shortage. And publicly-funded clinical trials are being suspended due to the shortages.”

A recent report from the Institute for Safe Medication Practices (ISMP) has uncovered a frightening number of near misses, patient harms and actual errors due to the drug shortages. It states that:

- One out of three reviewed facilities had a serious error that was caught in time — a near miss
- One out of four had an actual medication error resulting from the shortages
- One out of five reported actual adverse outcomes for patients

The September 23, 2010 issue of the ISMP Medication Safety Alert reported that survey respondents were alarmed by the:

- Increasing numbers of critically necessary medications in short supply
- Need to use unfamiliar alternative drugs — which are often more expensive
- Potential for mistakes and patient adverse events associated with alternative drugs or doses
- Lack of advance warning about impending shortages
- Time lost due to the management drug shortages



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How can there be shortages of long-used, life-saving medicines in the United States? A summit of manufacturers, oncologists, purchasers and regulatory officials held in November 2010 revealed – not surprisingly – that there’s no single reason or solution.

First, even generic injectable drugs are complicated and have long production time. Second, more than 80 percent of their ingredients come from outside the United States. Third, pharmaceutical company consolidations are often resulting in only one or two manufacturers for key drugs. If one of just two manufacturers has production problems or a disrupted international supply-chain of ingredients, that instantly creates a 50 percent shortage – which hits quickest in community and rural oncology practices that typically order small amounts of any one drug.

Finally, there is a lower profit margin in generics, as pharmaceutical companies race to make the new brand-name targeted therapies.

“If companies aren’t going to make money off these vital generic drugs, then they aren’t going to produce them,” said Bauman. “In that case, the Food and Drug Administration needs to allow importation; otherwise, patients won’t get the generic drugs they need, or will be forced to use much more expensive brand-name drugs.”

Fight Colorectal Cancer supports legislation introduced by Rep. Diana DeGette (D-CO) and Sens. Amy Klobuchar (D-MN) and Bob Casey (D-PA) that would put in place “early warning” systems, requiring manufacturers to notify the Food and Drug Administration (FDA) of any manufacturing or supply problems that could cause a drug shortage.

Longer-term fixes, which Fight Colorectal Cancer will continue to push for, include streamlining FDA procedures to allow importation of crucial drugs or quicker changes in ingredient sources; possible tax breaks to make vital lower-cost generic drugs more profitable; or even creating a national stockpile of vital drugs.